Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D0286922	**(X3) Date Survey Completed** 11/08/2022
Name of Provider or Supplier Genesiscare Usa Of Florida, Llc	**Street Address, City, State** 431 University Blvd, Jupiter, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	An announced recertification survey was conducted on 11/8/22 at Genesisicare USA of Florida, LLC, a clinical laboratory in Jupiter, Florida. Genesisicare USA of Florida, LLC is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory was not in compliance with Federal licensure requirements to perform testing for the analytes "Thyroid Stimulating Hormone (TSH) and Free T4 (thyroxine)" since testing began in August of 2021. The findings include: The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) obtained during survey showed the laboratory performs testing in the following specialty/subspecialties: Routine Chemistry and Hematology. The CLIA certificate provided at the time of survey confirmed the same specialties were on the license. Review of the laboratory test menu showed the laboratory performs testing for the analytes TSH and Free T4 on the Beckman Coulter Access 2 instrument. Review of the FDA (Food and Drug Administration) web site for CLIA testing complexity showed that since 2001, the FDA has classified the testing system "Beckman Coulter Access 2 Immunoassay System" for the analyte "Free T4" to be "Moderate Complexity" under the specialty of Endocrinology. In 2005, the FDA classified the Access 2 for the analyte "TSH" to be "Moderate Complexity" under the specialty of Endocrinology. The interview with Testing Person A on 11/8/22 at 11:00 am confirmed the laboratory was not licensed for Endocrinology and approximately 330 patients had been tested since August 30, 2021.